



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

September 12, 2000

**MEMORANDUM:**

**Subject** Efficacy Review for "Vesphene II SE " EPA Reg. No.1043-87  
Case No. 018805  
DP Barcode: D265662

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**Applicant:** Steris Corporation  
5035 Manchester Avenue  
St. Louis, MO 63110

**Formulation From Label:**

<u>Active Ingredient(s)</u>	<u>% by wt</u>
o-phenylphenol .....	9.09
p-tertiary amylphenol .....	7.66
<u>Inert Ingredient(s)</u> .....	83.25
Total .....	100.00



## BACKGROUND:

Product manager has requested an efficacy data and label review for "Vesphene IIse"(EPA Reg. No. 1043-87). This product is registered for use as a "one-step disinfectant as a germicidal detergent with fungicidal, virucidal, and tuberculocidal claims for use on hard, nonporous, environmental surfaces. The product is recommended for use only in industrial and institutional settings.

For a complete listing of the registered uses and claims refer to the last accepted label dated 08-27-1998 and the proposed label which is pinpunched 04-17-2000.

The current submission is an amendment application with confirmatory efficacy data to support a 14 day holding period for the end use dilution. The applicant had previously submitted a 14 day stability data to show chemical stability. The submitted 14 day shelf life data were generated and tested at a 1:128 dilution in the presence of 400 ppm of synthetic hard water and 5% organic soil. Efficacy data were also submitted to test product effectiveness for a 28 day shelf life.

1. (MRID #450998-01) "Official Methods of Analysis of the AOAC Use-Dilution Method, 15th Edition 1990" by Kathleen A. Baxter. Performing Laboratory: Hill Top Research, Main and Mill Streets, Miamiville Ohio 45147. Study completion date 03-17-2000

## RECOMMENDATIONS:

### Data Supported by the Submitted Data

1. (MRID # 4509989-01)

The submitted confirmatory efficacy data developed by the AOAC Use-Dilution Tests Methods appear adequate and satisfactory to support product 14 day shelf life effectiveness at a dilution of 1:128 in the presence of 5% sterile horse and 400 ppm of synthetic hard water in 10 minutes at 20°C when surfaces are thoroughly wetted by the solution and allowed to remain wet for 10 minutes.

1. Product effectiveness (14 day shelf life) was demonstrated against *Staphylococcus aureus* ATCC 6538, *Salmonella choleraesuis* ATCC 10708, and *Pseudomonas aeruginosa* ATCC 15442 under the test conditions indicated above.

## LABELING:

The following comments are applicable for the product proposed label pinpunched 04-17-2000.

1. Under the directions for use for the 14 day shelf life product, please clarify or provide additional information to whether the 14 day end solution is as effective in a dark container or does it matter whether the end use solution is stored in a clear glass storage bottle.
2. On the middle right panel and at the end of the statement, "This product is not to be used as a terminal sterilant..." add the following sentence: This product may be used to pre-clean or decontaminate critical or semicritical medical devices prior to sterilization or high level disinfection..."